

INFORMATION DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED OMB NO. 0579-0213 OMB NO. 0920-0576 EXP DATE 11/30/2015

INTRODUCTION

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS or CDC immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins:

Animal and Plant Health Inspection Service (APHIS) Agricultural Select Agent Program 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737

FAX: 301-734-3652

E-mail: ASAP@aphis.usda.gov

Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A-46 Atlanta, GA 30333 FAX: 404-718-2096

Email: form3@cdc.gov

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the **Responsible Official** (registered entities) or the **Laboratory Supervisor** (non-registered laboratories) to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

- Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).
- The **Responsible Official** (registered entities) or **Laboratory Supervisor** (non-registered entities) must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
 - For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and Appendix B and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
 - For reporting a release, complete sections 1, 2, and 3. For reporting a release that occurred during transfer, complete Sections 1, 2 and Appendix B and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
- The Responsible Official, Facility Director or the Laboratory Supervisor (non-registered laboratories) signs and sends the Form 3 to APHIS or CDC within 7 calendar days of the theft, loss, or release.
- Any laboratory (registered or non-registered) having questions regarding the Form 3 or submission of the Form 3, please send
 an e-mail to form3@cdc.gov. A member of the Form 3 Team from CDC or APHIS will contact you and provide assistance. A
 scenario based guidance document on theft, loss or release can be found on APHIS/CDC Form 3.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 851-3300 or CDC at (404) 718-2000. This guidance document and form are also available at http://www.selectagents.gov.